UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/272,821	03/20/1999	FATIH M. UCKUN	12152.55US01	6130

23552 7590 05/24/2004

MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903

EXAMINER	
TRAVERS, RUSSELL S	
ART UNIT	**PAPER NUMBER**
1617	

DATE MAILED: 05/24/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

UNITED STATES PATENT AND TRADEMARK OFFICE

COMMISSIONER FOR PATENTS
UNITED STATES PATENT AND TRADEMARK OFFICE
P.O. BOX 1450
ALEXANDRIA, VA 22313-1450
www.uspto.gov

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 20040513

MAILED

MAY 2 4 2004

GROUP

Application Number: 09/272,821
Filing Date: March 20, 1999
Appellant(s): UCKUN, FATIH M.

Ronald A. Daignault
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed February 17, 2004.

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is correct.

(4) Status of Amendments After Final

The amendment after final rejection filed on August 26, 2003 has not been entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is correct.

(7) Grouping of Claims

The appellant's statement in the brief that certain claims do not stand or fall together is not agreed with because although the claims are segregated into groups with respect to the instant rejection, the presented arguments deal with said claims as a group. Examiner is unsure how to distinguish the instant groups.

(9) Prior Art of Record

WO 93/03022 Lind et al 18 February 1993

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

The following is a quotation of the first paragraph of 35 U.S.C. § 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The specification is objected to under 35 U.S.C. § 112, first paragraph, as failing to adequately teach how to make and/or use the invention, and thereby failing to provide an enabling disclosure.

The instant specification fails to provide information that would allow the skilled artisan to practice the instant invention without undue experimentation. Attention is directed to *In re Wands*, 8 USPQ2d 1400 (CAFC 1988) at 1404 where the court set forth the eight factors to consider when assessing if a disclosure would have required undue experimentation. Citing *Ex parte Forman*, 230 USPQ 546 (BdApls 1986) at 547 the court recited eight factors:

1) the quantity of experimentation necessary,

2) the amount of direction or guidance provided,

3) the presence of absence of working examples,

4) the nature of the invention,

5) the state of the prior art,

6) the relative skill of those in the art

7) the predictability of the art, and

8) the breadth of the claims.

Applicant fails to set forth the criteria that allows the skilled artisan to identify those HIV strains "resistant to a chemotherapeutic agent". Additionally, Applicant fails to provide information allowing the skilled artisan to ascertain these compounds without undue experimentation. In the instant case, only a limited number of HIV strains "resistant to a chemotherapeutic agent" examples are set forth, thereby failing to provide sufficient working examples. It is noted that these examples are neither exhaustive, nor define the class of compounds required. The pharmaceutical art is unpredictable, requiring each embodiment to be individually assessed for physiological activity. The instant claims read on all HIV strains "resistant to a chemotherapeutic agent", necessitating an exhaustive search for the embodiments suitable to practice the claimed invention. Applicants fail to provide information sufficient to practice the claimed invention, absent undue experimentation.

Claims 23, 25, 26, 29, 30, 31, 34, 35 ,36, 39, 41 and 42 are rejected under 35 U.S.C. § 112, first paragraph, for the reasons set forth in the objection to the specification.

Claims 23, 25, 26, 29, 30, 31, 34, 35 ,36, 39, 41 and 42 are rejected under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 23, 25, 26, 29, 30, 31, 34, 35 ,36, 39, 41 and 42 are rendered indefinite by the phrase HIV strains "resistant to a chemotherapeutic agent" and thereby failing to clearly set forth the metes and bounds of the patent protection desired. Criteria defining HIV strains "resistant to a chemotherapeutic agent" are not set forth in the specification, thereby failing to provide information defining the instant inventions metes and bounds. Applicant's term fails to clearly define the subject matter encompassed by the instant claims, thus is properly rejected under 35 USC 112, second paragraph.

The following is a quotation of 35 U.S.C. § 103 which forms the basis for all obviousness rejections set forth in this Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) or (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.

Claims 23-44 are rejected under 35 U.S.C. § 103 as being unpatentable over Lind et al.

Lind et al and et al teach the claimed compounds as old and well known in combination with various pharmaceutical carriers and excipients in a dosage form. These medicaments are taught as useful for treating viral infections generally, specifically HIV, as herein claimed (see specifically page 15). Claims 23-44, and the primary reference, differ from the claimed invention by not reciting treatment of specific resistant HIV strains. Attention is directed to Lind et al page 3, lines 20-24 setting forth the issue of HIV resistance to conventional antiviral agents, and the concept the instant compounds overcome this problem. Possessing this teaching, the skilled artisan would see the instant compounds, taught as anti-HIV by Lind et al, as useful for treating resistant HIV strains, absent information to the contrary. .

It is generally considered prima facie obvious to employ compounds taught as inhibiting viral replication as therapeutic for this same condition. The idea for employing them flows logically from their having been used individually in the prior art. As shown by the recited teachings, the instant claims define nothing more than the use of conventional anti-HIV agents.

Those rebuttal arguments set forth in the response filed April 23, 2003 fail to address problems residing in the rejected claims. Although claims 24, 27, 28, 32, 33, 37, 40 and 43-44 provide those compounds of interest to individuals attempting to practice the instant claims, the rejected claims place the burden of undue experimentation on the public to ascertain those situations herein envisioned. Those

compounds, or levels of resistance, herein envisioned are neither specifically set forth, nor provided via guidance in the instant specification to the routeineer. Simply stated, the invention as set forth in the rejected claims is an invitation for the skilled artisan to experiment.

Attention is directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection.

Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Forcing the burden of undue experimentation on the skilled artisan fails to establish those metes and bounds envisioned for the instant invention. Absent meaningful limitations the instant claims fail to provide any criteria for identifying the limits of protection herein envisioned. Functional limitations relied on by Applicants fail to meet the required burden of notice place on those seeking to patent protection.

Again, Applicants aver unexpected benefits residing in the claimed subject matter, yet fail ~~to fails~~ to set forth evidence substantiating this belief. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Applicants is not clear, convincing or reasonably commensurate in scope with the instant claims. Absent a clear, convincing showing commensurate with a showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103.

It is well known by the skilled artisan that carriers and excipients are employed to enhance the activity of active ingredients. Thus, the skilled artisan would expect conventional excipients and carriers to be useful concomitantly, absent information to the contrary. The instant carriers and excipients are not employed concomitantly in the prior art, thus only obviate their concomitant use.

Applicant's attention is drawn to In re Graf, 145 USPQ 197 (CCPA 1965) and In re Finsterwalder, 168 USPQ 530 (CCPA 1971) where the court ruled that when a substance is unpatentable under 35 USC 103, it is immaterial that applicant may have disclosed an obvious or unobvious further purpose or advantage for the substance.

Examiner would favorably consider claims directed to those medicaments providing unexpected therapeutic benefits, as averred herein.

The instant claims are directed to effecting an old and well known therapeutic use with an old and well known compound, wherein a biochemical system may have been altered. Arguments that such claims are not directed to the old and well known ultimate utility for this compound are not probative. It is well settled patent law that mode of action elucidation does not impart patentable moment to otherwise old and obvious subject matter. Applicant's attention is directed to In re Swinehart, (169 USPQ 226 at 229) where the Court of Customs and Patent Appeals stated "is elementary that the mere recitation of a newly discovered function or property, inherently possessed by things in the prior art, does not cause a claim drawn to those things to distinguish over the prior art.". Additionally, where the Patent Office has reason to believe that a functional limitation asserted to be critical for establishing novelty in the claimed subject matter may, in fact, be an inherent characteristic of the prior art, it possesses the authority to requires the applicant to prove that the subject matter shown to be in the prior art dose not posses the characteristic relied on. In the instant invention, the claims are directed to the ultimate utility set forth in the prior art, albeit distanced by various biochemical intermediates. The ultimate utility for the claimed compounds is old

and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

(11) Response to Argument

Those rebuttal arguments set forth in the appeal brief filed February 27, 2004 fail to address problems residing in the rejected claims. Although claims 24, 27, 28, 32, 33, 37, 40 and 43-44 provide those compounds of interest to individuals attempting to practice the instant claims, the rejected claims place the burden of undue experimentation on the public to ascertain those situations herein envisioned. Those compounds, or levels of resistance, herein envisioned are neither specifically set forth, nor provided via guidance to the Routeieneer in the instant specification. Simply stated, the invention as set forth in the rejected claims is an invitation for the skilled artisan to experiment.

Attention is again directed to *General Electric Company v. Wabash Appliance Corporation et al* 37 USPQ 466 (US 1938), at 469, speaking to functional language at the point of novelty as herein employed: "the vice of a functional claim exists not only when a claims is "wholly" functional, if that is ever true, but when the inventor is painstaking when he recites what has already been seen, and then uses conveniently functional language at the exact point of novelty". Functional language at the point of novelty, as herein employed by Applicants, is further admonished in *University of California v. Eli Lilly and Co.* 43 USPQ2d 1398 (CAFC 1997) at 1406: stating this usage does "little more than outlin[e] goals appellants hope the recited invention achieves and

the problems the invention will hopefully ameliorate". Applicants functional language at the point of novelty fails to meet the requirements set forth under 35 USC 112, first paragraph. Claims employing functional language at the point of novelty, such as Applicants', neither provide those elements required to practice the inventions, nor "inform the public during the life of the patent of the limits of the monopoly asserted" *General Electric Company v. Wabash Appliance Corporation et* supra, at 468. Claims thus constructed provide no guidance as to medicaments employed, levels for providing therapeutic benefit, or provide notice for those practicing in the art, limits of protection. Simply stated, the presented claims are an invitation to experiment, not reciting a specific medicament regimen useful for practicing the instant invention.

Examiner notes the claims require the therapeutic agent to be employed only in those situations were a drug resistant HIV strain is encountered, not therapeutic failure flowing from some other cause. Thus, to practice the invention as claimed, and envisioned, the skilled artisan must in every case check the suspected etiological agent against all conventional anti-HIV agents to access the resistance profile. This requirement, absent guidance as to how this resistance profile can be easily deduced, forces the skilled artisan to engage in experimentation in every instance the invention is practiced: impermissible under current patent law. The cognate of this enablement problem is undue experimentation forced on the Routeineer precluding a clear determination of the instant claims metes and bounds. By requiring each disease situation to be assayed before the instant invention is practiced, the skilled artisan must assay the disease state to avoid practicing those claims set forth in Lind et al. Thus,

absent guidance, the skilled artisan must undertake experimentation in each instance to identify the instant inventions metes and bounds.

Forcing the burden of undue experimentation on the skilled artisan fails to establish those metes and bounds envisioned for the instant invention. Absent meaningful limitations, the instant claims fail to provide any criteria for identifying the limits of protection herein envisioned. Functional limitations relied on by Applicants fail to meet the required burden of notice placed on those seeking to patent protection.

Examiner finds Appellant's rebuttal arguments averring "obvious to try" or no "reasonable expectation of success" as fatally flawed. Attention is directed to claim 27 (pages 528-529) in Lind et al encompassing the compounds herein claimed. Additionally, Lind et al set forth the core structure of Appellants compound (see page 133, table A2, fifth compound). At page 539 (claim 57, V), R_d is halogen), Lind et al teach those compounds recited in the instant claims: halogen substituted pyridines: absent halogen, or oxy-methyl, substituted benzene. Those compounds recited by Lind are simply positional isomers of the compounds herein claimed, rendering such claims obvious over the Examiner cited prior art of record.

Although neither cited, nor suggested, Appellants appear to rely on the principle set forth by the Court in, *In re Baird* 29 USPQ2d 1550 (CAFC 1994). The Court stated, the" fact that a claimed compound may be encompassed by a disclosed generic formula does not by itself render that compound obvious", *In re Baird,* supra at page 1552 (see paragraph 1). In Baird, the compound was neither disclosed, nor claimed, a situation distinct from the instant case. Additionally, in Baird, the disclosure encompassed "more

than a 100 million different diphenols, only one of which was bisphenol A", *In re Baird, supra page 1552* (paragraph 3); the Baird fact pattern contrasts with the instant situation because in Lind et al a positional isomer is disclosed, and bio-assayed. Simply stated, the instant claimed compounds are at the very least, obvious over those compounds set forth by Lind et al.

Again, Applicants aver unexpected benefits residing in the claimed subject matter, yet fail to fails to set forth evidence substantiating this belief. Evidence as to unexpected benefits must be "clear and convincing" *In re Lohr*, 137 USPQ 548 (CCPA 1963), and be of a scope reasonably commensurate with the scope of the subject matter claimed, *In re Linder*, 173 USPQ 356 (CCPA 1972). The data provided by Applicants is not clear, convincing or reasonably commensurate in scope with the instant claims. Absent a clear, convincing showing commensurate with a showing of unexpected benefits, or a showing reasonably commensurate with the instant claims, such claims remain properly rejected under 35 USC 103.

As stated above, Lind et al teach compounds differing little from those herein claimed. Attention is directed to claim 27 (pages 528-529) setting forth the compounds herein claimed. Additionally, Lind et al set forth the core structure of Appellants compound (see page 133, table A2, fifth compound). At page 539 (claim 57, V), R_d is halogen) Lind et al teach compounds very closely related to those compounds recited in the instant claims: halogen substituted pyridines: albeit absent halogen, or oxy-methyl, substituted benzene. Those compounds recited by Lind are simply positional isomers of the compounds herein claimed, rendering such claims obvious over the

Examiner cited prior art of record. Examiner again notes the instant positional isomers are claimed, not simply disclosed, distinguishing the instant case from the facts of *In re Baird,* supra.

When attempting to illustrate unexpected benefits residing in a claimed compound; to employ the closest prior art compound as a comparison is de rigueur. In the instant case, Appellants have failed to employ the closest prior art compound to test for unexpected benefits residing in the compounds herein envisioned, and claimed. Absent comparison to the closest prior art, any attempts to illustrate unexpected benefits must fail. Examiner notes these compounds tested by Appellants are not the closest prior art compounds, but compounds distant from those set forth by Lind et al at page 539 (see compound V). Examiner notes Travertine (see appeal brief page 18) is not related to that compound taught by Lind et al at page 539. Thus, the presented attempt to illustrate unexpected benefits must fail.

To illustrate unexpected benefits residing in a compound, the skilled artisan must demonstrate an unexpected benefit residing in the claimed compounds. Unexpected benefits must therefore rise to a difference in kind, not a difference in degree, as herein provided. Examiner assumes RRT (see specification page 12) indicates inhibition of reverse transscriptase, a normal target or anti-HIV drugs, and a measure of HIV inhibition. Those values provided by Appellant attempting to illustrate unexpected inhibition differ little between the claimed compounds, and that compound proffered as the closest prior art. Additionally, Examiner notes other enzyme inhibition assays which should have been employed to illustrate unexpected benefits in the claimed

compounds, when compared to Travertine, were not undertaken. Simply stated, the data provided to illustrate unexpected benefits residing in the claimed compounds is unconvincing. The experiments failed to employ the closest prior art, and failed to show an unexpected therapeutic benefit residing in the claimed compounds. Absent unexpected benefits residing in the claimed compounds, when compared to the closest prior art compounds the instant provided data fails to overcome the obvious nature of the instant claims.

It is well known by the skilled artisan that carriers and excipients are employed to enhance the activity of active ingredients. Thus, the skilled artisan would expect conventional excipients and carriers to be useful concomitantly, absent information to the contrary

The ultimate utility for the claimed compounds is old and well known rendering the claimed subject matter obvious to the skilled artisan. It would follow therefore that the instant claims are properly rejected under 35 USC 103.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Russell Travers, J.D.,Ph.D
Primary Examiner
Art Unit 1617

rst
May 17, 2004

Conferees

SHENGJUN WANG
PRIMARY EXAMINER

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER

MERCHANT & GOULD PC
P.O. BOX 2903
MINNEAPOLIS, MN 55402-0903